K023344
1 of 3

NOV 6 2002

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to 21 CFR807.92(a).

Submitter Information

Chad Coberly
Bowel Management Systems, LLC
1886 South 14th Street, Suite 6
Fernandina Beach, FL 32034
Phone: (904)261-2169
Fax: (904)261-2172

Date: September 27, 2002

807.92(a)(2)

Trade Name:	Indwelling Fecal Management System- Non-Sterile
Common Name:	Rectal Irrigation Tube
Classification Name(s):	Tubes, Gastrointestinal
Classification Number:	78KNT

807.92(a)(3)

Predicate Device(s)

IFMS	Bowel Management Systems, LLC
Colo-Vage System	HDC Corp.
Virden Rectal Catheter	CR Bard
Leon's Fecal Tube	Leon's Fecal Tube Mfg.

Additional Substantial Equivalence Information is provided in the following substantial equivalence table.

510(k) Summary: Indwelling Fecal Management System
Bowel Management Systems, LLC

807.92(a)(5)

Intended Use(s)

Diversion of fecal matter to minimize external contact with the patient, to facilitate the c ollection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enemas/medications.

K023349
3 of 3

Comparison Chart for Substantial Equivalence

Function / Device Feature	IFMS -Non Sterile (Bowel Mgt Sys) (This Submission)	IFMS Catheter (Bowel Mgt Sys) K012113	Colo-Vage System (HDC Corp.) K841289	Virden Rectal Catheter (Bard) Exempt per 21CFR 876.5980	Fecal Sanitary Tube (Leon's Fecal Tube mfg.) K813526
Indications for Use	Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enema/medications.	Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enema/medications	Colonic Irrigation and drainage of fecal matter.	Administration of barium during radiopaque evaluation.	Collection of fecal Excretion.
Materials	Silicone	Silicone	Silicone	Natural Rubber	Natural Rubber
Bowel Retention	External balloon	External balloon	External balloon	External balloon	External Ring
Bowel Irrigation	Silicone Lumen with flared capped port termination	Silicone Lumen with flared capped port termination	Silicone lumen with flared termination	No Irrigation	No Irrigation
Enema/Medication Administration	Silicone Lumen with flared capped port termination	Silicone Lumen with flared capped port termination	Silicone lumen with flared termination	Natural rubber latex lumen with flared termination	No enema/medication administration
Port Access	Sampling/fluid administration	Sampling/fluid administration	Sampling/fluid administration	Not Specified	Not Specified
Sterile	No	Yes	Yes	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 2002

Mr. Chad A. Coberly
Director of Intellectual Property
and Business Development
Bowel Management Systems, LLC
1886 South 14th Street, Suite 6
FERNANDINA BEACH FL 32034

Re: K023344
Trade/Device Name: Indwelling Fecal Management System, Non-Sterile
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: September 27, 2002
Received: October 7, 2002

Dear Mr. Coberly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023344

Device Name: Indwelling Fecal Management System, Bowel Management Systems, LLC

Indications For Use:

Diversion of fecal mater to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enemas/medication.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023344